WO 03/104272 PCT/EP03/06096

Claims

5

10

1. A fusion partner protein comprising a choline binding domain and a heterologous promiscuous T helper epitope.

- A fusion partner protein according to claim 1 wherein the choline binding domain is derived from the C terminus of LytA.
- 3. A fusion partner protein according to claim 2 wherein the C-LytA or derivatives comprises at least four repeats of any of SEQ ID NO:1 to 6.
- 4. A fusion partner protein according to any of claims 1 to 3, wherein the choline binding domain is selected from the group comprising:
 - a) the C-terminal domain of LytA as set forth in SEQ ID NO:7; or
 - b) the sequence of SEQ ID NO:8; or
 - a peptide sequence comprising an amino acid sequence having at least 85% identity, preferably at least 90% identity, more preferably at least 95% identity, most preferably at least 97-99% identity, to any of SEQ ID NO:1 to 6; or
- d) a peptide sequence comprising an amino acid sequence having at least 15, 20, 30, 40, 50 or 100 contiguous amino acids from the amino acid sequence of SEQ ID NO:7 or SEQ ID NO:8.
 - 5. A fusion partner protein as claimed in any of claims 1 to 4 further comprising a heterologous protein.
- 20 6. A fusion protein as claimed in claim 5 wherein the heterologous protein is chemically conjugated the fusion partner.
 - 7. A fusion protein as claimed in claim 5 or 6 wherein the heterologous protein is derived from an organism selected from the following group: Human Immunodeficiency virus HIV-1, human herpes simplex viruses, cytomegalovirus, Rotavirus, Epstein Barr virus,
- Varicella Zoster Virus, from a hepatitis virus such as hepatitis B virus, hepatitis A virus, hepatitis C virus and hepatitis E virus, from Respiratory Syncytial virus, parainfluenza virus, measles virus, mumps virus, human papilloma viruses, flaviviruses or Influenza virus, from Neisseria spp, Moraxella spp, Bordetella spp; Mycobacterium spp., including M. tuberculosis; Escherichia spp, including enterotoxic E. coli; Salmonella spp,; Listeria spp; Helicobacter spp; Staphylococcus spp., including S. aureus, S. epidermidis;; Borrelia spp; Chlamydia spp., including C. trachomatis, C. pneumoniae; Plasmodium spp., including P. falciparum; Toxoplasma spp., Candida spp.
 - 8. A fusion protein as claimed in claim 5 or 6 wherein the heterologous protein is a tumour associated protein or tissue specific protein or immunogenic fragment thereof.
- A fusion protein as claimed in claim 8 wherein the heterologous protein or fragment thereof is selected from MAGE 1, MAGE 3, MAGE 4, PRAME, BAGE, LAGE 1, LAGE 2, SAGE, HAGE, XAGE, PSA, PAP, PSCA, prostein, P501S, HASH2, Cripto, B726,

WO 03/104272 PCT/EP03/06096

NY-BR1.1, P510, MUC-1, Prostase, STEAP, tyrosinase, telomerase, survivin, CASB616, P53, or her 2 neu.

- 10. A fusion protein as claimed in any of claims 6 to 9 further comprising an affinity tag of at least 4 histidine residues.
- 11. A nucleic acid sequence encoding a protein of claim 1 to 10.

10

15

20

30

- 12. An expression vector comprising a nucleic acid sequence of claim 11.
- 13. A host transformed with a nucleic acid sequence of claim 11 or with an expression vector of claim 12.
- 14. An immunogenic composition comprising a protein as claimed in any of claim 1 to 10 or a DNA sequence as claimed in claim 11 and a pharmaceutically acceptable excipient.
- 15. An immunogenic composition as claimed in claim 14 which additionally comprises a TH-1 inducing adjuvant.
- 16. An immunogenic composition as claimed in claim 15 in which the TH-1 inducing adjuvant is selected from the group of adjuvants comprising: 3D-MPL, QS21, a mixture of QS21 and cholesterol, a CpG oligonucleotide or a mixture of two or more said adjuvants.
- 17. A process for the preparation of a immunogenic composition as claimed in any of claims 14 to 16, comprising admixing the fusion protein of any of claims 6 to 10 or a the encoding polynucleotide of claim 11 with a suitable adjuvant, diluent or other pharmaceutically acceptable carrier.
- 18. A process for producing a fusion protein of any of claims 1 to 10 comprising culturing a host cell of claim 13 under conditions sufficient for the production of said fusion protein and recovering the fusion protein from the culture medium.
- 19. A protein of any of claims 1 to 10 or a DNA sequence of claim 11 for use in medicine.
 - 20. Use of a protein as claimed in any of claim 1 to 10 or a DNA sequence of claim 11 in the manufacture of an immunogenic composition for eliciting an immune response in a patient.
 - 21. Use according to claim 20, wherein said immune response is to be elicited by sequential administration of i) the said protein followed by the said DNA sequence; or ii) the said DNA sequence followed by the said protein.
 - 22. Use according to claim 21 wherein said DNA sequence is coated onto biodegradable beads or delivered via a particle bombardment approach.
 - 23. Use according to claim 21 or claim 22 wherein said protein is adjuvanted.
- 24. Use of a protein as claimed in any of claim 1 to 10 or a DNA sequence of claim 11 in the manufacture of an immunogenic composition for immunotherapeutically treating a patient suffering from or susceptible to cancer.

WO 03/104272 PCT/EP03/06096

25. Use according to claim 24 wherein said cancer is prostate cancer, colon cancer, lung cancer, breast cancer or melanoma.

- 26. A method of treating a patient suffering from cancer by administrating a safe and effective amount of a composition according to claim 12.
- 5 27. A method according to claim 26 wherein said cancer is prostate cancer, colorectal cancer, lung cancer, breast cancer or melanoma.